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NORTHERN DISTRICT OF CALIFORNIA

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA  
(SAN FRANCISCO DIVISION)

IN RE: BEXTRA AND CELEBREX  
MARKETING SALES PRACTICES AND  
PRODUCT LIABILITY LITIGATION

MDL No. 1699

LONNY BREYMAN

Case No. 07-4313

Plaintiffs

**CRB**

v.

CIVIL COMPLAINT

PFIZER, INC., PHARMACIA CORPORATION,  
and G.D. SEARLE LLC, (FKA G.D. SEARLE &  
CO.),

JURY TRIAL DEMANDED

Defendants.

Plaintiffs, by and through their undersigned counsel, bring this action for damages against Defendants PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.) (hereafter "Defendants") for damages arising from Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe prescription anti-inflammatory drug Celebcoxib, trade name CELEBREX® ("CELEBREX").

1     **I. PARTIES**

2                     1.     Plaintiff LONNY BREYMAN, is an adult individual residing in Murrieta,  
3     California. (Unless otherwise specified, hereinafter the term "Plaintiff" as used in the singular  
4     refers to all aforementioned Plaintiffs)

5                     2.     Defendant PFIZER, INC. ("PFIZER") is a Delaware corporation with its  
6     principal place of business in New York, New York. On July 16, 2002 PFIZER announced its  
7     proposed acquisition of PHARMACIA CORPORATION ("PHARMACIA"). On April 16, 2003,  
8     PFIZER completed its \$60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary  
9     of PFIZER, PHARMACIA acted in all aspects as PFIZER's agent and alter ego. At all relevant  
10    times, PFIZER and/or its predecessors in interest were engaged in the business of designing,  
11    testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug  
12    Celecoxib, under the trade name CELEBREX in Hawaii and throughout the United States.

13                    3.     Defendant G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.)  
14    ("SEARLE") is a Delaware corporation with its principal place of business in Illinois. In April  
15    2000 SEARLE was acquired by PHARMACIA, and became a wholly-owned subsidiary of  
16    PHARMACIA. At the time of PFIZER's acquisition of PHARMACIA, SEARLE was a wholly-  
17    owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this  
18    Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE  
19    has been engaged in the business of designing, testing, manufacturing, packaging, marketing,  
20    distributing, promoting, and selling the drug Celecoxib, under the trade name CELEBREX in  
21    Hawaii and California and throughout the United States.

22                    4.     Defendant PHARMACIA is a Delaware corporation with its principal  
23    place of business in New Jersey. PHARMACIA was created in April 2000 through the merger of  
24    Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit. PHARMACIA is  
25    now a wholly-owned subsidiary of PFIZER. At all relevant times, PHARMACIA, and its  
26    predecessors in interest have been engaged in the business of designing, testing, manufacturing,  
27    packaging, marketing, distributing, promoting, and selling the drug Celecoxib, under the trade  
28

1 name CELEBREX in Hawaii and California and throughout the United States.

2 5. Celecoxib was developed in 1998 by SEARLE and marketed jointly by  
3 SEARLE and PFIZER under the brand name CELEBREX. SEARLE was acquired by  
4 PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full  
5 control of CELEBREX.

6 6. At all times relevant to this action, Defendants intentionally, recklessly  
7 and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects,  
8 and disadvantages of CELEBREX, and advertised, promoted, marketed, sold and distributed  
9 CELEBREX as a safe prescription medication when, in fact, Defendants had reason to know, and  
10 did know, that CELEBREX was not safe for its intended purposes, for the patients for whom it  
11 was prescribed, and for whom it was sold; and that CELEBREX caused serious medical  
12 problems, and in certain patients, catastrophic injuries and deaths.

13 7. In engaging in the conduct alleged herein, each Defendant acted as the  
14 agent for each of the other Defendants, or those Defendant's predecessors in interest.

15 **II. JURISDICTION AND VENUE**

16 8. This Court has subject matter jurisdiction over this matter pursuant to  
17 28 U.S.C.A. § 1332 (diversity jurisdiction). The amount in controversy exceeds \$75,000.00 and  
18 there is complete diversity of citizenship between Plaintiff and Defendants.

19 9. Venue is proper in this District pursuant to 28 U.S.C.A. § 1391.  
20 Defendants marketed, advertised and distributed the dangerous product in this district, thereby  
21 receiving substantial financial benefit and profits from sales of the dangerous product in this  
22 district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

23 10. At all relevant times herein, Defendants were in the business of designing,  
24 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and  
25 selling their product, CELEBREX. Defendants at all times relevant hereto designed, developed,  
26 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce  
27 (including Hawaii and California) the aforementioned prescription drug. Defendants do  
28

1 substantial business in the States of Hawaii and California and within this District, advertise in  
2 this district, receive substantial compensation and profits from sales of CELEBREX in this  
3 District, and made material omissions and misrepresentations and breaches of warranties in this  
4 District so as to subject them to *in personam* jurisdiction in this District. In engaging in the  
5 conduct alleged herein, each Defendant acted as the agent for each of the other Defendants or  
6 those Defendant's predecessors in interest.

### 7 **III. INTERDISTRICT ASSIGNMENT**

8 11. Assignment to the Northern District of California, San Francisco Division,  
9 is proper pursuant to MDL-1699, Pretrial Order No. 2 dated December 13, 2005, as this action is  
10 related to *In Re: Bextra and CELEBREX Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699,  
11 assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on  
12 September 6, 2005.

### 13 **IV. FACTUAL BACKGROUND**

#### 14 **A. Facts Common to All Plaintiffs**

15 12. Plaintiff was prescribed and ingested CELEBREX.

16 13. As a direct and proximate result of using CELEBREX, Plaintiff suffered  
17 severe cardiovascular and/or cerebrovascular injuries.

18 14. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's  
19 injury unaware—and could not have reasonably known or have learned through reasonable  
20 diligence—that such injury directly resulted from Plaintiff's ingestion of CELEBREX and  
21 Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations.

22 15. Plaintiff used CELEBREX in a proper and reasonably foreseeable manner  
23 and used it in a condition that was substantially the same as the condition in which it was  
24 manufactured and sold.

25 16. Plaintiff would not have purchased and used CELEBREX had Defendants  
26 properly disclosed the risks associated with the drug, and through diligent effort was not able to  
27 discover the risk from CELEBREX prior to Plaintiff's use of the drug.



1           **B.     Facts Regarding CELEBREX: Science And Other Cox-2 Inhibitors**

2           17.     CELEBREX is among a class of pain medications called non-steroidal  
3 anti-inflammatory drugs (“NSAIDs”). Aspirin, naproxed (trade name Aleve<sup>®</sup>), and ibuprofen  
4 (trade name Advil<sup>®</sup>) are examples of well-known NSAIDs.

5           18.     NSAIDs reduce pain and inflammation by blocking the body’s production  
6 of pain transmission enzymes called cyclooxygenase, COX-1 and COX-2. COX enzymes trigger  
7 the sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are  
8 important cogs in the physiology of pain, igniting hormone-like actions in the immediate vicinity  
9 of the cells that release them, thereby inducing inflammation, pain, and fever.

10          19.     Because COX enzymes and prostaglandins increase the pain associated  
11 with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable  
12 target for pain-management drugs.

13          20.     Traditional NSAIDs like aspirin, ibuprofen and naproxen inhibit both  
14 COX-1 and COX-2 enzymes simultaneously, providing relief from inflammation and pain, but at  
15 the cost of potential adverse gastrointestinal effects, as the prostaglandins that are supported by  
16 COX-1 enzymes are involved in the production of gastric mucus which protects the stomach wall  
17 from the hydrochloric acid present in the stomach. By blocking the COX-1 enzyme, the body’s  
18 ability to protect gastric tissue is hampered and, as a result, can cause harmful gastrointestinal  
19 side effects, including stomach ulceration and bleeding.

20          21.     Defendants and other pharmaceutical companies set out to remedy these  
21 gastrointestinal side effects suffered by some NSAID users by developing “selective” inhibitors,  
22 called coxibs, which targeted only COX-2 production, thus (allegedly) allowing for proper  
23 maintenance of gastric tissue while still reducing inflammation. Their development was based on  
24 the hypothesis that COX-2 was the source of prostaglandins E2 and I2, which mediate  
25 inflammation, and that COX-1 was the source of the same prostaglandins in the stomach lining.  
26 By not inhibiting COX-1, whose products provide cytoprotection in the gastric epithelium, these  
27 coxibs were thought to decrease the incidence of gastric side effects when compared to traditional  
28 NSAIDS that inhibit both COX-1 and COX-2.

1                   22. In making this decision, however, Defendants and their predecessors in  
2 interest either intentionally ignored and/or recklessly disregarded current medical knowledge that  
3 selective COX-2 inhibition lowers prostaglandin I2 levels, the predominant COX-2 product  
4 responsible for preventing platelet aggregation and clotting, while leaving thromboxane A2, the  
5 potent COX-1 platelet aggregator and vasoconstrictor, unaffected. By selectively inhibiting  
6 prostaglandin I2 without similarly suppressing its COX-1 counterpart, CELEBREX and other  
7 coxibs expose their users to a host of clot-related cardiovascular risks, including heart attack,  
8 stroke, and unstable angina.

9                   23. On June 29, 1998, SEARLE and PFIZER filed for FDA approval of  
10 Celecoxib, its first major COX-2 inhibitor drug, under the trade name CELEBREX. The FDA  
11 granted preliminary approval of the new drug on December 31, 1998 for the relief of signs and  
12 symptoms of adult osteoarthritis and rheumatoid arthritis. A year later, on December 23, 1999,  
13 the FDA granted accelerated approval of CELEBREX for a second indication; the reduction of  
14 intestinal polyps as an adjunct to endoscopy and surgery in patients with familial adenomatous  
15 polyposis (FAP), a rare genetic disorder.

16                   24. In late January 1999, following FDA approval, PFIZER publicly launched  
17 CELEBREX, their new “blockbuster” drug, in one of the largest direct-to-consumer marketing  
18 campaigns ever undertaken for prescription drugs. PFIZER’s massive marketing campaign  
19 fraudulently and misleadingly depicted CELEBREX as a much safer and more effective pain  
20 reliever than less inexpensive traditional NSAIDs. Defendants and their representatives and  
21 agents misrepresented the safety profile of CELEBREX to consumers, the medical community,  
22 healthcare providers, and third party payors.

23                   **C. Facts Regarding Celebrex’s Safety And Defendants’ Knowledge Thereof**

24                   25. The potential for cardiovascular risk of selective COX-2 inhibitors was  
25 known to Defendants long before the FDA granted market approval in December 1998. By 1997,  
26 and prior to the submission of the New Drug Application (the “NDA”) for CELEBREX,  
27 Defendants were aware that, by selectively inhibiting only the COX-2 enzyme, CELEBREX  
28

1 altered the homeostatic balance between prostacyclin synthesis and thromboxane and thereby  
2 increased the prothrombotic effects of the drugs, causing blood clots to form in those who  
3 ingested it. See Topol, E.J., *et al.*, "Risk of Cardiovascular Events Associated with Selective Cox-  
4 2 Inhibitors," JAMA, August 22, 2001 at 954.

5 26. Pharmacologist Dr. Garrett Fitzgerald of the University of Pennsylvania  
6 reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004,  
7 that contemporaneous with Defendants' launch it was known that selective COX-2 inhibitors,  
8 such as CELEBREX, suppressed the formation of prostaglandin I-2 in healthy volunteers,  
9 inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or  
10 thrombotic stroke. Fitzgerald, G.A., Patrono C., "The Coxibs, Selective Inhibitors of  
11 Cyclooxygenase-2," N Engl J Med 2001;345:433-442.

12 27. Early FDA updates in March and April of 1999 similarly acknowledged  
13 this known risk, but noted, based upon PFIZER's representations, that CELEBREX "does not  
14 affect platelet aggregation (clumping), an important part of the blood clotting process." See FDA  
15 Updates, "New Arthritis Drug May Have Fewer Side Effects," FDA Consumer March-April  
16 1999.

17 28. Based on the studies performed on CELEBREX, other COX-2 inhibitors,  
18 and basic research on this type of selective inhibitor which had been widely conducted,  
19 Defendants knew when CELEBREX was being developed and tested that selective COX-2  
20 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific  
21 additional threat to anyone with existing heart disease or cardiovascular risk factors.

22 29. Despite years of studies on selective COX-2 inhibitors, as well as the  
23 disturbing new studies specifically analyzing the risks of CELEBREX, Defendants failed to take  
24 any action to protect the health and welfare of patients, opting instead to continue promoting the  
25 drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and  
26 Arthritis Drug Advisory Committee meetings.

1           **D.     CELEBREX and Cox-2 Studies Did Not Show CELEBREX to be Safe**

2                 **1.     CELEBREX Long-Term Arthritis Safety Study (CLASS)**

3                 30.     In September 1998, PHARMACIA sponsored an allegedly independent  
4 CELEBREX Long-Term Arthritis Safety Study ("CLASS"). The multicenter, double-blind,  
5 parallel group study sought to compare the incidence of clinically significant upper  
6 gastrointestinal events between CELEBREX 400 mg BID and Ibuprofen 800 mg. (CLASS data  
7 is found in NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. CLASS  
8 was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA  
9 Medical Officer) on September 20, 2000.)

10                31.     On September 13, 2000, Defendants released the results of the CLASS  
11 study in the *Journal of American Medicine*. Silverstein, F.E., *et al.*, "*Gastrointestinal Toxicity*  
12 *with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid*  
13 *Arthritis: The CLASS Study: A Randomized Controlled Trial*," 284 JAMA 1247 (2000).  
14 Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer  
15 complications combined, as well as other clinically supported toxic effects, compared with  
16 NSAIDs at standard doses."

17                32.     Although Defendants touted the CLASS study as the primary evidence to  
18 support its theory that CELEBREX was safer for consumers who could not tolerate traditional  
19 NSAIDs in their gastrointestinal system, Defendants intentionally, recklessly and/or negligently  
20 concealed, suppressed, omitted, and misrepresented the results, risks and defects of the CLASS  
21 study. Among other things, Defendants failed to release the study's complete twelve month  
22 results releasing only the first six months of trials, reported biased and misleading results, limited  
23 conclusions to upper gastrointestinal events despite other known risks factors, and understated  
24 known cardiovascular risks.

25                33.     Despite Defendants' favorable CLASS Study conclusions, no other  
26 reviewing or administrative body was able to substantiate those findings. The FDA Medical  
27 Officer Review of the CLASS data found CELEBREX to be no more efficacious than other  
28 traditional NSAIDs comparators. *See generally*, FDA Medical Officer Review, NDA 20-998/S-



1 009 submitted to the FDA by SEARLE on June 12, 2000. According to the FDA's review of the  
2 CLASS data: "Celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or  
3 either comparator (diclofenac and ibuprofen) with regards to the primary safety endpoint of  
4 CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in the trial  
5 although there were trends that favored celecoxib." (FDA CLASS Review).

6 34. The FDA Arthritis Advisory Committee similarly found no "clinically  
7 meaningful" safety advantage of CELEBREX over older NSAIDs. (FDA CDER Arthritis  
8 Advisory Committee, February 7th and 8th, 2001, Gaithersburg, Maryland). The CLASS Study  
9 failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on  
10 this information, the Committee advised that further studies be done to assess the risk of COX-2  
11 drugs and NSAIDS when taken with aspirin.

12 35. In a June 2002 editorial, the *British Medical Journal* chastised the Study's  
13 "misleading" and "seriously biased" nature; noting that the complete results "clearly  
14 contradict[ed] the published conclusions," and warning against the dangers of "overoptimistic,"  
15 "short-term" data and "post hoc changes to the protocol." Juni, Peter, *et. at.*, "Are Selective COX  
16 2 Inhibitors Superior To Traditional Non Steroidal Anti-Inflammatory Drugs?" *BMJ*  
17 2002;324:1287-1288. Most noticeably, the CLASS study considered only six months of data  
18 despite the fact that researchers at that point had 12 months of data that, when analyzed as a  
19 whole, showed no significant difference. Instead of releasing the complete 12-month results  
20 from CLASS, PFIZER relied on and published only the first six months of data. *JAMA* 2000,  
21 48:1455-1460. The results of the completed study revealed the real truth: CELEBREX offered no  
22 gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the  
23 second half of the CLASS trials were in users of CELEBEX. These results clearly contradict the  
24 published CLASS conclusions.

25 36. Editors of the Journal of the American Medical Association (JAMA) and  
26 other medical experts were reportedly "flabbergasted" when they realized they had been "duped"  
27 by only being provided with the first six months of CLASS data. Okie S., "Missing data on  
28

1 *Celebrex: Full study altered picture of drug,*” Washington Post 2001 Aug 5;Sect A:11. The  
2 *Washington Post* reported JAMA editors noting: “When all of the data were considered, most of  
3 CELEBREX’s apparent [GI] safety advantage disappeared.”

4 37. Institutional bias also appeared to play a role in the Study’s biased  
5 conclusions. According to the *Washington Post*, all sixteen CLASS authors were either  
6 employees of PHARMACIA or paid consultants of the company. Okie, S., “*Missing data on*  
7 *Celebrex: Full study altered picture of drug,*” Washington Post 2001 Aug 5;Sect A:11. Moreover,  
8 at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he  
9 was duped by PHARMACIA. In the summer of 2000, *The Journal of the American Medical*  
10 *Association* asked Wolfe to participate in the “six-month” trial. Wolfe found the study, tracking  
11 8,000 patients over a six-month period, persuasive, and penned a favorable review, which helped  
12 to drive up CELEBREX sales. It was not until early the next year, while serving on the FDA’s  
13 Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months,  
14 as the company had originally led both Wolfe and the *Journal* to believe. *Id.* Here again, when  
15 the complete data was considered, most of CELEBREX advantages disappeared.

16 38. Defendants also limited conclusions of the CLASS study to upper  
17 gastrointestinal events, despite other known risks factors, and understated known cardiovascular  
18 risks. A metastudy by the Cleveland Clinic published in the *Journal of the American Medical*  
19 *Association* analyzed data from two major studies, including CLASS, funded by the drug  
20 companies and two smaller ones—all for cardiovascular risks. Debabrata Mukherjee, *et al.*, “*Risk*  
21 *of Cardiovascular Events Associated with Selective Cox-2 Inhibitors,*” 286 JAMA 954 (2001).  
22 The metastudy found that PHARMACIA failed to identify and study cardiovascular risks for their  
23 products. The annualized heart attack rates for patients taking Vioxx or Celebrex, the researchers  
24 found, were “significantly higher” than those in a group taking placebos. “The available data raise  
25 a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors,” they concluded.

26 39. “A total of 36 deaths occurred during the [CLASS] study or during post  
27 study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen  
28

1 group . . . . Most deaths were cardiovascular in nature.” FDA CLASS Review at 54. The  
2 increased number of adverse cardiovascular events in the CELEBREX group was not surprising,  
3 as they were also revealed in the original New Drug Application (NDA) submitted for  
4 CELEBREX. “In the original NDA, myocardial infarction was noted to occur at a higher rate in  
5 celecoxib-treated as compared to placebo treated patients. In the long term trial (Trial 024) that  
6 was included in the NDA submission, the predominate (>90%) cause of death for patients taking  
7 celecoxib at any dose was cardiovascular.” FDA CLASS Review at 78.

8 40. Public Citizen, a public watchdog organization, also reviewed the CLASS  
9 data in its entirety. A complete review reveals the combined anginal adverse events was 1.4% in  
10 the CELEBREX group versus 1.0% in either NSAID group. Specifically, the rate of heart attack  
11 in the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

12 41. Eric Topol of the Cleveland Clinic reached a similar conclusion, noting that  
13 the CLASS trial MI rate was 1.6% in CELEBREX group (at a dosage of 400 mg twice a day) and  
14 1.2% in the ibuprofen group for the 1739 patients taking low-dose aspirin. Topol noted that this  
15 numerical excess, albeit not statistically significant, was also found in the 6229 patients not  
16 taking aspirin in the trial. Eric J. Topol, “*Arthritis Medicines and Cardiovascular Events –*  
17 *House of Coxibs*,” JAMA 293:366. Based on this data, Topol and his colleagues concluded: “It  
18 is mandatory to conduct a trial specifically assessing cardiovascular morbidity.” *Id.*  
19 Unfortunately, no such trials were ever initiated, delaying the official warnings of CELEBREX  
20 and jeopardizing countless lives in the process.

21 42. The CLASS data proves that PFIZER knew that its first generation COX-2  
22 inhibitor, CELEBREX, caused a disproportionately and statistically significant high number of  
23 adverse cardiovascular events before it was introduced to the market in January 1999. According  
24 to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the  
25 cardiovascular risks of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial  
26 was intended to be this placebo-controlled trial of CELEBREX.

27 **2. APC Trial**  
28

1                   43. In early 2000, the National Cancer Institute (NCI), in collaboration with  
2 SEARLE and PFIZER, initiated the Adenoma Prevention with Celecoxib (APC) trial, a  
3 randomized, double-blind, placebo-controlled study to discover the efficacy of CELEBREX in  
4 preventing the growth of pre-cancerous colon polyps. N.ENG. J. MED. 352;11 at 1072. The trial  
5 involved 2026 patients across the country with randomization to one of three groups: (1) placebo;  
6 (2) 200 mg CELEBREX twice daily; and (3) 400 mg CELEBREX twice daily. The patients, each  
7 of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of  
8 33 months while taking the study drug, with the primary objective of limiting the development of  
9 colorectal cancer.

10                   44. On December 17, 2004, the National Cancer Institute suspended the use of  
11 CELEBREX for all participants in the APC trial due to "significant excess of cardiovascular  
12 death, myocardial infarction (MI) and stroke." Eric J. Topol, "*Arthritis Medicines and*  
13 *Cardiovascular Events – House of Coxibs*," JAMA 293:366. Analysis by an independent Data  
14 Safety Monitoring Board (DSMB) showed a two to three fold increased risk of major fatal and  
15 non-fatal cardiovascular events for participants taking the drug compared to those on a placebo  
16 with a secondary dose-response effect.

17                   45. The absolute excess of major cardiovascular events of 13/1000 patients at  
18 the 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with rofecoxib and  
19 valdecoxib, both selective NSAID COX-2 inhibitors removed for the market for their significant  
20 cardiovascular risks. Eric J. Topol, "*Arthritis Medicines and Cardiovascular Events – House of*  
21 *Coxibs*," JAMA 293:366.

22                   46. The FDA reported similar results, noting:

23  
24                   In the National Cancer Institute's Adenoma Prevention with  
25 Celecoxib (APC) trial in patients at risk for recurrent colon  
26 polyps, a 2-3 fold increased risk of serious adverse CV  
27 events was seen for CELEBREX compared to placebo after  
28 a mean duration of treatment of 33 months. There appeared  
to be a dose response relationship, with a hazard ratio of 2.5  
for CELEBREX 200 mg twice daily and 3.4 CELEBREX  
400 mg twice daily for the composite endpoint of death  
from CV causes, myocardial infarction (MI), or stroke.



1 April 7, 2005 FDA Alert: [www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm](http://www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm).

2 47. The dosage noted in the study is itself important for two reasons: first,  
3 there appears to be an association between dosage and the increase in adverse cardiovascular  
4 events; second, most patients increase dosage. PFIZER knew patients were increasing their  
5 dosages as noted in the CLASS Study: "Interestingly ... up to 70% of patients increased their dose  
6 for celecoxib." FDA CLASS Review at 74. Thus, PFIZER was aware of "dosage creep."

7 **3. Other CELEBREX Trials**

8 48. Several other CELEBREX trials also gave Defendants insight into the  
9 cardiovascular risks esented by CELEBREX. The Prevention of Spontaneous Adenomatous  
10 Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke,  
11 heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7%  
12 for placebo.

13 49. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which  
14 reflected "the combined rate of all serious cardiovascular adverse events in patients getting a  
15 placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold  
16 increase in CV risk in those people taking celecoxib. (p=0.03)." *Public Citizen*, January 26,  
17 2005, Dr. Sidney M. Wolfe. According to Dr. Sidney Wolfe, "The study revealed a significantly  
18 increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV  
19 deaths in people using celecoxib compared to those using placebo." *Id.*

20 **4. Cox-2 Studies: VIGOR and APPROVe**

21 50. PFIZER also had access to other data which indicated a cardiovascular risk  
22 with its drugs. Specifically, PFIZER had knowledge of two studies conducted by Merck related  
23 to its Cox-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and  
24 Adenomatous Polyp Prevention (APPROVe).

25 **b. VIGOR**

26 51. In 2000, The FDA Medical Officer Review of CLASS specifically noted  
27 the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS  
28 Review at 78.

1                   52. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes  
2 Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically  
3 significant); they experienced 4.6 times more hypertension events serious enough to warrant  
4 discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure  
5 adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice  
6 the risk of naproxen and the results were considered statistically significant.

7                   53. The VIGOR study comprised the most definitive scientific evidence ever  
8 obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold  
9 standard of medical research. It was a safety study with endpoints set in advance. As Merck  
10 stated many times, it was designed to provide definite proof of safety, convincing enough to  
11 silence the most skeptical critics. In medical terms, the VIGOR results raised the question of  
12 whether selective inhibition of COX-2 was a monumental mistake from the start. While the  
13 NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the  
14 cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All  
15 makers of NSAIDs, including Defendants, were aware of these results.

16                   **c. APPROVe**

17                   54. Anxious to put safety questions surrounding Vioxx to rest, Merck designed  
18 another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test  
19 the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular  
20 safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of  
21 the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and  
22 "doubled the risk of MI (myocardial infarction a/k/a heart attack)<sup>1</sup>. *Public Citizen*, January 24,  
23 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx,  
24 PFIZER never paused to reevaluate the CELEBREX data and studies.

25                   55. The scientific data available during and after CELEBREX's approval

26 \_\_\_\_\_  
27 <sup>1</sup> Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe  
28 trial did not emerge until after patients had been taking the drug for 18 months, closer analysis  
indicates that significant increase in risk of heart attack was evident in as little as 4 months time.

1 process made clear to Defendants that their formulation of CELEBREX would cause a higher risk  
2 of blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them  
3 to the need to do additional and adequate safety studies.

4 56. As stated by Dr. Topol on October 21, 2004, in *The New England Journal*  
5 *of Medicine*, outlining Defendants' failure to have conducted the necessary trials before  
6 marketing to humans "it is mandatory to conduct a trial specifically assessing cardiovascular risk  
7 and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with  
8 established coronary artery disease, who frequently have coexisting osteoarthritis requiring  
9 medication and have the highest risk of further cardiovascular events."

10 57. Dr. Topol was also the author on the study published in August 2001 in  
11 JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in  
12 persons who used COX-2 inhibitors.

13 58. Based upon readily available scientific data, Defendants knew, or should  
14 have known, that their pre-approval testing of CELEBREX did not adequately represent the  
15 cross-section of individuals who were intended consumers and therefore, likely to take  
16 CELEBREX. Therefore, Defendants' testing and studies were grossly inadequate.

17 59. Had Defendants done adequate testing prior to approval and market launch,  
18 rather than the extremely short duration studies done on the small size patient base that was  
19 actually done, the Defendants' scientific data would have revealed significant increases in  
20 incidence of strokes and myocardial infarctions among the intended and targeted population of  
21 CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed  
22 serious side effects. Defendants should have taken appropriate measures to ensure that their  
23 defectively designed product would not be placed in the stream of commerce and/or should have  
24 provided full and proper warnings accurately and fully reflecting the scope and severity of  
25 symptoms of those side effects should have been made.

26 60. In fact, post-market approval data did reveal increased risks of clotting,  
27 stroke and myocardial infarction, but Defendants intentionally suppressed this information in  
28

1 order for them to gain significant profits from continued CELEBREX sales.

2 61. Defendants' failure to conduct adequate testing and/or additional testing  
3 prior to market launch was based upon their desire to generate maximum financial gains for  
4 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2  
5 inhibitor market.

6 62. At the time Defendants manufactured, advertised, and distributed  
7 CELEBREX to consumers, Defendants intentionally or recklessly ignored and/or withheld  
8 information regarding the increased risks of hypertension, stroke and/or myocardial infarctions  
9 because Defendants knew that if such increased risks were disclosed, consumers would not  
10 purchase CELEBREX, but instead would purchase other cheaper and safer NSAIDs.

11 **E. Facts Regarding Defendants' Marketing And Sale Of CELEBREX**

12 63. Such an ineffective and unreasonably dangerous drug could only be widely  
13 prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the  
14 Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and  
15 misleading advertising, consumers, including the Plaintiff, would not have purchased  
16 CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

17 64. Defendant's marketing was so fraudulent that the FDA issued three  
18 Warning Letters to Defendants in October 1999, April 2000, and November 2000, all finding that  
19 Defendants were unlawfully making false or misleading statements concerning the safety and/or  
20 efficacy of CELEBREX. The November letter cited two direct-to-consumer television  
21 advertisements that overstated the efficacy of CELEBREX. The FDA ordered that SEARLE  
22 immediately cease distribution of the misleading ads.

23 65. On February 2001, the FDA issued a Warning Letter to PHARMACIA  
24 stating that promotional activities from marketing CELEBREX were unlawful because they were  
25 "false, lacking in fair balance, or otherwise misleading." The FDA found that CELEBREX had  
26 been promoted for unapproved uses, in unapproved dosing regimens, and that the marketers had  
27 made unsupportable claims that CELEBREX was safer and more effective than other NSAIDs.  
28



1                   66. In August 2001, it was revealed that PHARMACIA had misrepresented the  
2 results of a post-marketing clinical study of CELEBREX when submitting it for publication.  
3 PHARMACIA selectively omitted portions of the data relating to adverse effects. The  
4 *Washington Post* reported on August 5, 2001 that, “the study had lasted a year, not six months as  
5 . . .thought. Almost all of the ulcer complications that occurred during the second half of the  
6 study were in CELEBREX users. When all of the data were considered, most of CELEBREX’s  
7 apparent safety advantage[as compared to traditional NSAIDs] disappeared.”

8                   67. On January 10, 2005 the FDA again issued PFIZER a written reprimand  
9 for its promotional activities. The reprimand reads: “These five promotional pieces  
10 [3 CELEBREX and 2 Bextra] variously: omit material facts . . . and make misleading safety,  
11 unsubstantiated superiority, and unsubstantiated effectiveness claims.” Amid continued  
12 frustration with PFIZER’s continually misleading marketing strategy and ever surmounting  
13 evidence of cardiovascular dangers, the FDA Advisory Panel voted overwhelmingly that the  
14 company should never again advertise the drug [CELEBREX].”

15                   68. At all times relevant herein, Defendants engaged in a marketing campaign  
16 with the intent that consumers would perceive CELEBREX as a safer and better drug than its  
17 other NSAIDs and, therefore, purchase CELEBREX.

18                   69. Defendants widely and successfully marketed CELEBREX throughout the  
19 United States by, among other things, conducting promotional campaigns that misrepresented the  
20 efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was  
21 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.  
22 Defendants made misrepresentations by means of media advertisements, and statements  
23 contained in sales literature provided to Plaintiff’s prescribing physicians.

24                   70. Despite knowledge of the dangers presented by CELEBREX, Defendants  
25 and Defendants’ predecessors in interest, through their officers, directors and managing agents for  
26 the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to  
27 remedy the known defects of CELEBREX and failed to warn the public, including Plaintiff, of  
28

1 the serious risk of injury occasioned by the defects inherent in CELEBREX. Defendants and  
2 their officers, agents and managers intentionally proceeded with the inadequate safety testing, and  
3 then the manufacturing, sale and marketing of CELEBREX, knowing that persons would be  
4 exposed to serious potential danger, in order to advance their own pecuniary interests.  
5 Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety  
6 of the public and particularly of Plaintiff.

7  
8 71. In an elaborate and sophisticated manner, Defendants aggressively  
9 marketed CELEBREX directly to consumers and medical professionals (including physicians and  
10 leading medical scholars) in order to leverage pressure on third party payors, medical care  
11 organizations, and large institutional buyers (*e.g.*, hospitals) to include CELEBREX on their  
12 formularies. Faced with the increased demand for the drug by consumers and health care  
13 professionals that resulted from Defendants' successful advertising and marketing blitz, third  
14 party payors were compelled to add CELEBREX to their formularies. Defendants' marketing  
15 campaign specifically targeted third party payors, physicians, and consumers, and was designed  
16 to convince them of both the therapeutic and economic value of CELEBREX.

17 72. Defendants represented that CELEBREX was similar to ibuprofen and  
18 naproxen but was superior because it lacked any of the common gastrointestinal adverse side  
19 effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS").  
20 Defendants promoted CELEBREX as a safe and effective alternative that would not have the  
21 same deleterious and painful impact on the gut, but that would be just as effective, if not more so,  
22 for pain relief.

23 73. Yet, CELEBREX possessed dangerous and concealed or undisclosed side  
24 effects, including the increased risk of serious cardiovascular events, such as heart attacks,  
25 unstable angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events,  
26 such as strokes. In addition, CELEBREX, which is significantly more expensive than traditional  
27 NSAIDs<sup>2</sup>, was actually was no more effective than traditional and less expensive NSAIDs and,

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28 <sup>2</sup> The cost of Celebrex is at least \$3-\$6 per day, while an over-the-counter NSAID can cost \$.50 or less per day.

1 just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding.  
2 Yet, Defendants chose not to warn about these risks and dangers.

3 74. Defendants knew of these risks before the U.S. Food and Drug  
4 Administration (the "FDA") approved CELEBREX for sale, but Defendants ignored,  
5 downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy  
6 in its promotion, advertising, marketing, and sale of CELEBREX. Defendants' omission,  
7 suppression, and concealment of this important information enabled CELEBREX to be sold to,  
8 and purchased, or paid for by, the Consumers at a grossly inflated price.

9 75. Consequently, CELEBREX captured a large market share of anti-  
10 inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX  
11 exceeded \$2 billion, despite the significantly higher cost of CELEBREX as compared to other  
12 pain relievers in the same family of drugs.

13 76. Because Defendants engaged in a promotional and marketing campaign  
14 that featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a  
15 safer drug than other drugs in its class, while uniformly failing to disclose the health risks of  
16 CELEBREX, Defendants were able to justify pricing CELEBREX significantly higher than the  
17 cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed  
18 the truth about CELEBREX, Defendants would not and could not have reaped the billions of  
19 dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission,  
20 suppression, and obfuscation of the truth.

21 77. The Defendants intentionally, deliberately, knowingly, and actively  
22 concealed, omitted, suppressed, and obfuscated important and material information regarding the  
23 risks, dangers, defects, and disadvantages of CELEBREX from Plaintiff, the public, the medical  
24 community, and the regulators. This concealment and omission was deliberate, knowing, active,  
25 and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and  
26 prevented Plaintiff from obtaining all the material information that would be important to her  
27 decision as a reasonable person to purchase, pay for, and/or use CELEBREX.  
28

1           78. Defendants' systematic, active, knowing, deliberate, and uniform  
2 concealment, omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or  
3 use CELEBREX; and caused Plaintiff's losses and damages as asserted herein.

4           79. Had Defendants done adequate testing prior to approval and "market  
5 launch," the defendants' scientific data would have revealed significant increases in stroke and  
6 myocardial infarction amongst the intended population of CELEBREX consumers. Adequate  
7 testing would have shown that CELEBREX possessed serious side effects. Defendants should  
8 have taken appropriate measures to ensure that their defectively designed product would not be  
9 placed in the stream of commerce and/or should have provided full and proper warnings  
10 accurately and fully reflecting the scope and severity of symptoms of those side effects should  
11 have been made.

12           80. In fact, post-market approval data did reveal increased risks of clotting,  
13 stroke and myocardial infarction, but Defendants intentionally suppressed this information in  
14 order for them to gain significant profits from continued CELEBREX sales.

15           81. Defendants' failure to conduct adequate testing and/or additional testing  
16 prior to "market launch," and active concealment and failure to warn the medical community and  
17 general public of the known cardiovascular risks of CELEBREX was particularly negligent,  
18 reckless and/or malicious given the drug's known target market. Defendants were well aware  
19 that most patients taking CELEBREX are elderly and have higher risk of developing  
20 cardiovascular risks to begin with. Nearly half of the patients with arthritis have coexisting  
21 cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to  
22 higher dosing.

23           82. Defendants' failure to conduct adequate testing and/or additional testing  
24 prior to "market launch" was based upon their desire to generate maximum financial gains for  
25 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2  
26 inhibitor market.

27           83. At the time Defendants manufactured, advertising, and distributed  
28



1 CELEBREX to consumers including Plaintiff, Defendants intentionally or recklessly ignored  
2 and/or withheld information regarding the increased risks of hypertension, stroke and/or  
3 myocardial infarctions because Defendants knew that if such increased risks were disclosed,  
4 consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer  
5 NSAID drugs.

6  
7 **CLAIMS FOR RELIEF**

8 **FIRST CLAIM FOR RELIEF**

9 **Negligence**

10 84. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
11 as if fully set forth herein.

12 85. Defendants owed Plaintiff a duty to exercise reasonable care when  
13 designing, manufacturing, marketing, advertising, distributing, and selling CELEBREX. This  
14 duty included the duty not to introduce a pharmaceutical drug, such as CELEBREX, into the  
15 stream of commerce that caused users to suffer from unreasonable, dangerous or untoward  
16 adverse side effects.

17 86. At all relevant times to this action, Defendants owed a duty to properly  
18 warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical  
19 drug CELEBREX.

20 87. Defendants breached their duties by failing to exercise ordinary care in the  
21 preparation, design, research, testing, development, manufacturing, inspection, labeling,  
22 marketing, promotion, advertising and selling of CELEBREX, including:

23 (a) failing to use due care in the preparation and development of  
24 CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were  
25 ingested;

26 (b) failing to use due care in the design of CELEBREX to prevent the  
27 aforementioned risk of injuries to individuals when the drugs were ingested;

28 (c) failing to conduct adequate pre-clinical testing and research to  
determine the safety of CELEBREX;

1 (d) failing to conduct adequate post-marketing surveillance and  
2 exposure studies to determine the safety of CELEBREX;

3 (e) failing to completely, accurately and in a timely fashion, disclose  
4 the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff,  
5 consumers, the medical community, and the FDA;

6 (f) failing to accompany CELEBREX with proper warnings regarding  
7 all possible adverse side effects associated with the use of CELEBREX;

8 (g) failing to use due care in the manufacture, inspection, and labeling  
9 of CELEBREX to prevent the aforementioned risk of injuries to individuals who used  
10 CELEBREX;

11 (h) failing to use due care in the promotion of CELEBREX to prevent  
12 the aforementioned risk of injuries to individuals when the drugs were ingested;

13 (i) failing to use due care in the sale and marketing of CELEBREX to  
14 prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

15 (j) failing to use due care in the selling of CELEBREX to prevent the  
16 aforementioned risk of injuries to individuals when the drugs were ingested;

17 (k) failing to provide adequate and accurate training and information to  
18 the sales representatives who sold CELEBREX;

19 (l) failing to provide adequate and accurate training and information to  
20 healthcare providers for the appropriate use of CELEBREX; and

21 (m) being otherwise reckless, careless and/or negligent.

22 88. Despite the fact that Defendants knew or should have known that  
23 CELEBREX caused unreasonable and dangerous side effects which many users would be unable  
24 to remedy by any means, Defendants continued to promote and market CELEBREX to  
25 consumers, including Plaintiff, when safer and more effective methods of pain relief were  
26 available.

27 89. Defendants were, or should have been had they exercised reasonable care,  
28

1 in possession of evidence demonstrating that CELEBREX caused serious side effects.  
2 Nevertheless, they continued to market their products by providing false and misleading  
3 information with regard to the safety and efficacy of CELEBREX.

4 90. Defendants knew or should have known that consumers such as Plaintiff  
5 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described  
6 above.

7 91. As a direct and proximate consequence of Defendants' acts, omissions, and  
8 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
9 required and will require healthcare and services; has incurred and will continue to incur medical  
10 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
11 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
12 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
13 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
14 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
15 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

16 92. Defendants' conduct was committed with knowing, conscious, wanton,  
17 willful, and deliberate disregard for the value of human life and the rights and safety of  
18 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
19 as to punish Defendants and deter them from similar conduct in the future.

20 93. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
21 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
22 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

23 **SECOND CLAIM FOR RELIEF**  
24 **Strict Liability**

25 94. Plaintiff incorporates by reference all previous paragraphs of this  
26 Complaint as if fully set forth herein and further alleged as follows:

27 95. At all times relevant to this action, Defendants were suppliers of  
28 CELEBREX, placing the drug into the stream of commerce. CELEBREX was expected to and

1 did reach Plaintiff without substantial change in the condition in which it was manufactured and  
2 sold.

3 96. CELEBREX was unsafe for normal or reasonably anticipated use.

4 97. CELEBREX was defective in design or formulation because when it left  
5 the hands of the manufacturer and/or supplier, it was unreasonably dangerous and more  
6 dangerous than an ordinary consumer would expect. CELEBREX was also defective and  
7 unreasonably dangerous in that the foreseeable risk of injuries from CELEBREX exceeded the  
8 benefits associated with the design and/or formulation of the product.

9 98. CELEBREX is unreasonably dangerous: (a) in construction or  
10 composition; (b) in design; (c) because an adequate warning about the product was not provided;  
11 (d) because it does not conform to an express warranty of the manufacturer about the product .

12 99. CELEBREX as manufactured and supplied by Defendants was also  
13 defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and  
14 inadequate reporting regarding the results of the clinical trials, testing and study. Defendants  
15 failed to perform adequate testing before exposing Plaintiff to the medication, testing which  
16 would have shown that CELEBREX had the potential to cause serious side effects including the  
17 injuries suffered like the Plaintiff.

18 100. CELEBREX as manufactured and supplied by Defendants was defective  
19 due to inadequate post-marketing warnings or instructions because, after Defendants knew or  
20 should have known of the risk of injuries from CELEBREX, they failed to provide adequate  
21 warnings to the medical community and the consumers, to whom they were directly marketing  
22 and advertising CELEBREX; and, further, it continued to affirmatively promote CELEBREX as  
23 safe and effective.

24 101. CELEBREX was manufactured, distributed, tested, sold, marketed,  
25 advertised and promoted defectively by Defendants, and as a direct and proximate cause of  
26 Defendants' defective design of CELEBREX, Plaintiff used CELEBREX rather than other safer  
27 and cheaper NSAIDs. As a result, Plaintiff suffered the personal injuries described herein.  
28



1           102. Information given by Defendants to the medical community and to the  
2 consumers concerning the safety and efficacy of CELEBREX, especially the information  
3 contained in the advertising and promotional materials, did not accurately reflect the potential  
4 side effects of CELEBREX.

5           103. Had adequate warnings and instructions been provided, Plaintiff would not  
6 have taken CELEBREX, and would not have been at risk of the harmful side effects described  
7 herein.

8           104. Defendants acted with conscious and deliberate disregard of the  
9 foreseeable harm caused by CELEBREX.

10          105. Plaintiff could not, through the exercise of reasonable care, have  
11 discovered CELEBREX's defects or perceived the dangers posed by the drug.

12          106. As a direct and proximate consequence of Defendants' acts, omissions, and  
13 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
14 required and will require healthcare and services; has incurred and will continue to incur medical  
15 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
16 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
17 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
18 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
19 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
20 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

21          107. Defendants' conduct was committed with knowing, conscious, wanton,  
22 willful, and deliberate disregard for the value of human life and the rights and safety of  
23 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
24 as to punish Defendants and deter them from similar conduct in the future.

25          108. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
26 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
27 suit and attorneys' fees and such other and further relief as this Court deems just and proper.  
28

**THIRD CLAIM FOR RELIEF**  
**Breach of Express Warranty**

109. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

110. Defendants expressly represented to Plaintiff and other consumers and the medical community that CELEBREX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

111. These warranties came in the form of:

(a) Defendants' public written and verbal assurances of the safety and efficacy of CELEBREX;

(b) Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for CELEBREX, which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX, especially to the long-term ingestion of CELEBREX;

(c) Verbal and written assurances made by Defendants regarding CELEBREX and downplaying the risk of injuries associated with the drug;

(d) False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing CELEBREX during the period of Plaintiff's ingestion of CELEBREX, and;

(e) Advertisements.

112. The documents referred to above were created by and at the direction of Defendants.

113. Defendants knew or had reason to know that CELEBREX did not conform to these express representations in that CELEBREX is neither as safe nor as effective as represented, and that CELEBREX produces serious adverse side effects.

114. CELEBREX did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-

1 of side effects, and causes severe and permanent injuries.

2 115. Plaintiff, other consumers, and the medical community relied upon  
3 Defendants' express warranties.

4 116. As a direct and proximate consequence of Defendants' acts, omissions, and  
5 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
6 required and will require healthcare and services; has incurred and will continue to incur medical  
7 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
8 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
9 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
10 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
11 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
12 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

13 117. Defendants' conduct was committed with knowing, conscious, wanton,  
14 willful, and deliberate disregard for the value of human life and the rights and safety of  
15 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
16 as to punish Defendants and deter them from similar conduct in the future.

17 118. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
18 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
19 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

20 **FOURTH CLAIM FOR RELIEF**  
21 **Breach of Implied Warranty**

22 119. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
23 as if fully set forth herein.

24 120. Defendants manufactured, distributed, advertised, promoted, and sold  
25 CELEBREX.

26 121. At all relevant times, Defendants knew of the use for which CELEBREX  
27 was intended and impliedly warranted the product to be of merchantable quality and safe and fit  
28

1 for such use.

2 122. CELEBREX was not of merchantable quality and was not fit for its  
3 intended use, because it causes increased risk of serious cardiovascular and cerebrovasclar  
4 adverse events, including heart attacks, strokes and other serious and harmful adverse health  
5 effects.

6 123. Defendants breached the implied warranty that CELEBREX was of  
7 merchantable quality and fit for such use in violation of Md. Code Ann., Com. Law § 2-314, *et*  
8 *seq.*

9 124. Defendants were aware that consumers, including Plaintiff, would use  
10 CELEBREX for treatment of pain and inflammation and for other purposes.

11 125. Plaintiff and the medical community reasonably relied upon Defendants'  
12 judgment and expertise to only sell them or allow them to prescribe CELEBREX only if it was  
13 indeed of merchantable quality and safe and fit for its intended use. Consumers, including  
14 Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for  
15 CELEBREX.

16 126. CELEBREX reached consumers, including Plaintiff, without substantial  
17 change in the condition in which it was manufactured and sold by Defendants.

18 127. Defendants breached their implied warranty to consumers, including  
19 Plaintiff; CELEBREX was not of merchantable quality or safe and fit for its intended use.

20 128. As a direct and proximate consequence of Defendants' acts, omissions, and  
21 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
22 required and will require healthcare and services; has incurred and will continue to incur medical  
23 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
24 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
25 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
26 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
27 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
28



1 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

2 129. Defendants' conduct was committed with knowing, conscious, wanton,  
3 willful, and deliberate disregard for the value of human life and the rights and safety of  
4 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
5 as to punish Defendants and deter them from similar conduct in the future.

6 130. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
7 compensatory damages and punitive and exemplary damages together with interest, the costs of  
8 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

9  
10 **FIFTH CLAIM FOR RELIEF:**  
**Fraudulent Misrepresentation & Concealment**

11 131. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
12 as if fully set forth herein.

13 132. Defendants' superior knowledge and expertise, their relationship of trust  
14 and confidence with doctors and the public, their specific knowledge regarding the risks and  
15 dangers of CELEBREX, and their intentional dissemination of promotional and marketing  
16 information about CELEBREX for the purpose of maximizing its sales, each gave rise to the  
17 affirmative duty to meaningfully disclose and provide all material information about  
18 CELEBREX's risks and harms to doctors and consumers.

19 133. Defendants made fraudulent affirmative misrepresentations with respect to  
20 CELEBREX in the following particulars:

21 (a) Defendants represented through their labeling, advertising,  
22 marketing materials, detail persons, seminar presentations, publications, notice letters, and  
23 regulatory submissions that CELEBREX had been tested and found to be safe and effective for  
24 the treatment of pain and inflammation; and

25 (b) Defendants represented that CELEBREX was safer than other  
26 alternative medications.

27 134. Defendants made affirmative misrepresentations; and fraudulently,  
28

1 intentionally and/or recklessly concealed material adverse information regarding the safety and  
2 effectiveness of CELEBREX.

3 135. Defendants made these misrepresentations and actively concealed adverse  
4 information at a time when Defendants knew or had reason to know that CELEBREX had defects  
5 and was unreasonably dangerous and was not what Defendants had represented to the medical  
6 community, the FDA and the consuming public, including Plaintiff.

7 136. Defendants omitted, suppressed and/or concealed material facts concerning  
8 the dangers and risk of injuries associated with the use of CELEBREX including, but not limited  
9 to, the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'  
10 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the  
11 serious nature of the risks associated with the use of CELEBREX in order to increase its sales.

12 137. The representations and concealment were undertaken by Defendants with  
13 an intent that doctors and patients, including Plaintiff, rely upon them.

14 138. Defendants' representations and concealments were undertaken with the  
15 intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to  
16 induce and encourage the sale of CELEBREX.

17 139. Defendants' fraudulent representations evinced their callous, reckless,  
18 willful, and depraved indifference to the health, safety, and welfare of consumers, including  
19 Plaintiff.

20 140. Plaintiff's physician and Plaintiff relied on and were induced by  
21 Defendants' misrepresentations, omissions, and/or active concealment of the dangers of  
22 CELEBREX in selecting CELEBREX treatment.

23 141. Plaintiff and the treating medical community did not know that the  
24 representations were false and were justified in relying upon Defendants' representations.

25 142. Had Plaintiff been aware of the increased risk of side effects associated  
26 with CELEBREX and the relative efficacy of CELEBREX compared with other readily available  
27 medications, Plaintiff would not have taken CELEBREX as Plaintiff did.  
28

1           143. As a direct and proximate consequence of Defendants' acts, omissions, and  
2 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
3 required and will require healthcare and services; has incurred and will continue to incur medical  
4 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
5 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
6 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
7 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
8 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
9 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

10           144. Defendants' conduct was committed with knowing, conscious, wanton,  
11 willful, and deliberate disregard for the value of human life and the rights and safety of  
12 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
13 as to punish Defendants and deter them from similar conduct in the future.

14           145. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
15 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
16 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

17                           **SIXTH CLAIM FOR RELIEF**  
18                           **(Unjust Enrichment)**

19           146. Plaintiff incorporates by reference all previous paragraphs of this  
20 Complaint as if fully set forth herein.

21           147. At all times relevant to this action, Defendants were the manufacturers,  
22 sellers, and/or suppliers of CELEBREX.

23           148. Plaintiff paid for CELEBREX for the purpose of managing her pain safely  
24 and effectively.

25           149. Defendants have accepted payment from Plaintiff for the purchase of  
26 CELEBREX.

27           150. Plaintiff did not receive the safe and effective pharmaceutical product for  
28

1 which Plaintiff paid.

2 151. It is inequitable and unjust for Defendants to retain this money because the  
3 Plaintiff did not in fact receive the product Defendant represented CELEBREX to be.

4 152. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
5 equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court  
6 deems just and proper.

7  
8 **SEVENTH CLAIM FOR RELIEF**  
**(Violations of State Consumer Fraud and Deceptive Trade Practices Acts)**

9 153. Plaintiff incorporates by reference the preceding paragraphs as if they were  
10 fully set forth herein.

11 154. Defendants had a statutory duty to refrain from unfair or deceptive acts or  
12 practices in the sale and promotion of CELEBREX to Plaintiff.

13 155. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and  
14 misleading acts or practices in violation of all Hawaii's consumer protection laws, identified  
15 below. Through its false, untrue and misleading promotion of CELEBREX, Defendants induced  
16 Plaintiff to purchase and/or pay for the purchase of CELEBREX. Defendants misrepresented the  
17 alleged benefits and characteristics of CELEBREX; suppressed, concealed and failed to disclose  
18 material information concerning known adverse effects of CELEBREX; misrepresented the  
19 quality of CELEBREX as compared to much lower-cost alternatives; misrepresented and  
20 advertised that CELEBREX was of a particular standard, quality or grade that it was not;  
21 misrepresented CELEBREX in such a manner that later, on disclosure of the true facts, there was  
22 a likelihood that Plaintiff would have switched from CELEBREX to another NSAID and/or  
23 chosen not to purchase and/or reimburse for purchases of CELEBREX; advertised CELEBREX  
24 with the intent not to sell it as advertised; and otherwise engaged in fraudulent and deceptive  
25 conduct.

26 156. Defendants' conduct created a likelihood of, and in fact caused, confusion  
27 and misunderstanding. Defendants' conduct misled, deceived and damaged Plaintiff and  
28



1 Defendants' fraudulent, misleading and deceptive conduct was perpetrated with an intent that  
2 Plaintiff rely on said conduct by purchasing and/or paying for purchases of CELEBREX.  
3 Moreover, Defendants knowingly took advantage of Plaintiff who was reasonably unable to  
4 protect her interests due to ignorance of the harmful adverse effects of CELEBREX. Defendants'  
5 conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable  
6 and substantially injurious to Plaintiff and offends the public conscience.

7 157. Plaintiff purchased primarily for personal, family or household purposes.

8 158. As a result of Defendants' violative conduct, Plaintiff purchased and/or  
9 paid for purchases of CELEBREX that were not made for resale.

10 159. Defendants engaged in unfair competition or deceptive acts or practices in  
11 violation of California B&P Code Section 17200, *et seq.*

12 160. As a proximate result of Defendants' misrepresentations and omissions,  
13 Plaintiff and Plaintiff have suffered ascertainable losses, in an amount to be determined at trial.

14 161. Throughout the period described in this Complaint, Defendants repeatedly  
15 engaged in intentional misconduct characterized by trickery, deceit and a wanton, willful,  
16 conscious and reckless disregard of the health, rights and interests of the Plaintiff, and, in so  
17 conducting itself, acted with oppression, fraud, and malice toward the Plaintiff. As a result of  
18 Defendants' indifference to and reckless disregard of the health and safety of CELEBREX  
19 patients, they suffered both physical and economic harm, and all end-payors incurred economic  
20 damages. Accordingly, Defendants' conduct was highly reprehensible under controlling Supreme  
21 Court punitive damages authority, and Plaintiff is entitled to punitive and/or exemplary damages.

22 162. As a direct and proximate consequence of Defendants' acts, omissions, and  
23 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
24 required and will require healthcare and services; has incurred and will continue to incur medical  
25 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
26 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
27 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
28

1 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
2 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
3 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

4 163. Defendants' conduct was committed with knowing, conscious, wanton,  
5 willful, and deliberate disregard for the value of human life and the rights and safety of  
6 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
7 as to punish Defendants and deter them from similar conduct in the future.

8 164. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
9 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
10 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

11  
12 **EIGHT CLAIM FOR RELIEF;**

13 **Survival Action- As to the VENDERMAN Plaintiff only**

14 178. Plaintiff incorporates by reference all previous paragraphs of this Complaint  
15 as if fully set forth herein.

16 179. Plaintiffs incurred special damages in the form of the reasonable value of  
17 services rendered for medical care for the injuries that Decedent sustained prior to Decedent's  
18 death, all caused by the ingestion of CELEBREX. A cause of action for recovery of such  
19 damages of Decedent's successor in interest survives death.

20  
21 180. Defendant acted in conscious disregard for the safety of Decedent with  
22 respect to matters alleged herein. Said disregard resulted in injuries and special damages, and  
23 warrants recovery of punitive damages by Decedent's successor in interest against said  
24 Defendant. The aforementioned damages survive Decedents death.

25  
26 **PRAYER FOR RELIEF**

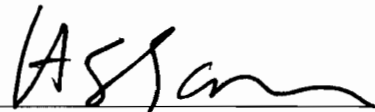
27 WHEREFORE, Plaintiff requests the following relief:  
28

1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Punitive and exemplary damages;
6. Pre-judgment and post-judgment interest as provided by law;
7. Recovery of Plaintiff's costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action;
8. Medical expenses, past and future, according to proof at time of trial;
9. For past and future mental and emotional distress, according to proof;
10. Loss of earnings and impaired earning capacity according to proof at the time of trial;
11. Damages for loss of care, comfort, society and companionship in an amount within the jurisdiction of this Court and according to proof;
12. Recovery of Decedent's costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action;
13. Pre-judgment and post-judgment interest as provided by law; and
14. Such other and further relief as the Court deems just and proper.

1 Dated: September 18, 2007

GANCEDO & NIEVES, LLP

2  
3 By:



Hector G. Gancedo

4 Hector G. Gancedo (SB# 132139)

5 Tina B. Nieves (SB# 134384)

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9 Attorneys for Plaintiffs



**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: September 18, 2007

GANCEDO & NIEVES, LLP

By: 

Hector G. Gancedo

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